MAR 16 2005

510(k) Summary
PMT Corporation
Endomark™ Sterile India Ink

1. SPONSOR

PMT Corporation
1500 Park Road
Chanhassen, MN 55317

Contact : Eric Caille
Phone: 952-470-0866

Date Prepared: October 19, 2004

2. DEVICE NAME

Proprietary Name: Endomark™ Sterile India Ink
Common/Usual Name: Colon marker
Classification Name: Colon marker

3. PREDICATE DEVICE

- Spot Endoscopic Marker (K993951)

4. DEVICE DESCRIPTION

The Endomark™ Sterile India Ink is a sterile, non-pyrogenic ink designed to be used as an endoscopic marker for marking polyps and lesions in the gastrointestinal tract. It is supplied in single-use 10 mL vials.

5. INTENDED USE

The Endomark™ Sterile India Ink is indicated for endoscopically marking lesions in the GI tract when the endoscopist anticipates the lesion will require surgical removal within thirty days.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Endomark™ Sterile India Ink is substantially equivalent to the predicate colon marker. The Endomark™ Sterile India Ink and the predicate device have the same indications for use. Both are carbon black formulations that are used for endoscopically tattooing or marking the colon.

7. PERFORMANCE TESTING

Information submitted in this premarket notification to support the safety and effectiveness of the Endomark™ Sterile India Ink includes results of chemical analysis, biocompatibility testing, and clinical experience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Mr. James R. Veale
Vice President, Strategic and Technical Assistance
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K042901
Trade/Device Name: Endomark™ Sterile India Ink
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 NBG
Dated: February 7, 2005
Received: February 8, 2005

Dear Mr. Veale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042901

Indications for Use

510(k) Number (if known):

Device Name: Endomark™ Sterile India Ink

Indications for Use:

The Endomark™ Sterile India Ink is indicated for endoscopically marking lesions in the GI tract when the endoscopist anticipates the lesion will require surgical removal within thirty days.

Prescription Use ___X___ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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